

SPECIALTY GUIDELINE MANAGEMENT

BOTOX (onabotulinumtoxin A)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
2. Urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
3. Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer)
4. Treatment of upper limb spasticity in adult patients
5. Treatment of lower limb spasticity in adult patients
6. Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
7. Treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
8. Cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain
9. Severe primary axillary hyperhidrosis that is inadequately managed with topical agents in adult patients
10. Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

B. Compendial Uses

1. Achalasia
2. Chronic anal fissures
3. Essential tremor
4. Excessive salivation
5. Hemifacial spasm
6. Spasmodic dysphonia (laryngeal dystonia)
7. Oromandibular dystonia
8. Myofascial pain syndrome
9. Focal hand dystonia
10. Facial myokymia
11. Hirschsprung disease with internal sphincter achalasia
12. Orofacial tardive dyskinesia
13. Painful bruxism
14. Palatal myoclonus
15. First bite syndrome
16. Palmar or gustatory (Frey's syndrome) hyperhidrosis

17. Myofascial pain syndrome

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. CRITERIA FOR INITIAL APPROVAL

A. Blepharospasm

Authorization of 12 months may be granted for treatment of blepharospasm.

B. Cervical dystonia

Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis) when there is sustained head torsion and/or tilt with limited range of motion.

C. Chronic migraine prophylaxis

Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:

1. Member experiences headaches \geq 15 days per month with headaches lasting longer than 4 hours,
2. Member completed an adequate trial of three oral migraine preventative therapies coming from at least 2 of the following classes with a trial of each medication at least 60 days in duration:
 - i. Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine)
 - ii. Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)
 - iii. Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)
 - iv. Calcium channel blockers (e.g., amlodipine, diltiazem, felodipine).
3. Members headache has at least two of the following:
 - i. Aggravated by routine movement
 - ii. Moderate to severe pain intensity
 - iii. Pulsating
 - iv. Unilateral
4. Members headache has at least one of the following:
 - i. Nausea/vomiting
 - ii. Sensitivity to light
 - iii. Sensitivity to sound

D. Overactive bladder with urinary incontinence

Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence, urgency, and frequency when all of the following criteria are met:

1. The member has tried and failed behavioral therapy.
2. The member has had an inadequate response or experienced intolerance to two anticholinergic medications (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).

E. Primary axillary, palmar, and gustatory (Frey's syndrome) hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis when all of the following criteria are met:

1. Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines); and
2. Significant disruption of professional and/or social life has occurred because of excessive sweating; and
3. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

F. Strabismus

Authorization of 12 months may be granted for treatment of strabismus when interference with normal visual system development is likely to occur and spontaneous recovery is unlikely.

Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

G. Upper limb spasticity

Authorization of 12 months may be granted for treatment of upper limb spasticity.

H. Lower limb spasticity

Authorization of 12 months may be granted for treatment of lower limb spasticity.

I. Urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)

Authorization of 12 months may be granted for treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met;

1. The member has tried and failed behavioral therapy
2. The member has had an inadequate response or experienced intolerance to an anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).

J. Achalasia

Authorization of 12 months may be granted for treatment of achalasia when the member has tried and failed conventional therapy such as pneumatic dilation and surgical myotomy.

K. Chronic anal fissures

Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates.

L. Essential tremor

Authorization of 12 months may be granted for treatment of essential tremor.

M. Excessive salivation

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

N. Hemifacial Spasm

Authorization of 12 months may be granted for treatment of hemifacial spasm.

O. Spasmodic dysphonia (laryngeal dystonia)

Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

P. Oromandibular dystonia

Authorization of 12 months may be granted for treatment of oromandibular dystonia.

Q. Myofascial Pain Syndrome

Authorization of 12 months may be granted for treatment of myofascial pain syndrome when the member has tried and failed all of the following:

1. Physical therapy
2. Injection of local anesthetics into trigger points
3. Injection of corticosteroids into trigger points

R. Focal hand dystonia

Authorization of 12 months may be granted for the treatment of focal hand dystonias.

S. Facial myokymia

Authorization of 12 months may be granted for the treatment of facial myokymia.

T. Hirschsprung disease with internal sphincter achalasia

Authorization of 12 months may be granted for the treatment of Hirschsprung's disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy.

U. Orofacial tardive dyskinesia

Authorization of 12 months may be granted for the treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine).

V. Painful bruxism

Authorization of 12 months may be granted for the treatment of painful bruxism when the member has had an inadequate response to a night guard and has had an inadequate response to pharmacologic therapy such as diazepam.

W. Palatal myoclonus

Authorization of 12 months may be granted for the treatment of palatal myoclonus when the member has disabling symptoms (e.g., intrusive clicking tinnitus) who had an inadequate response to clonazepam, lamotrigine, carbamazepine or valproate.

X. First bite syndrome

Authorization of 12 months may be granted for the treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants.

IV. CONTINUATION OF THERAPY

- A. All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria for all approvable conditions other than chronic migraine prophylaxis.
- B. Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the member has achieved or maintained a reduction in monthly headache frequency since starting therapy with Botox.

V. REFERENCES

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